PTO/SB/08A (08-00)

Approved for use through 10/31/2002 OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 No parsons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449/A/PTO

JAN 2 2 2004 37 INFORMATION DISCLOSUSE

STATEMENT BY APPLIE ANT

(use as many sheets as necessary

of 2 Sheet 1

| Cor                    | nplete if Known           |
|------------------------|---------------------------|
| Application Number     | 09/877,802                |
| Filing Date            | June 6, 2001              |
| First Named Inventor   | Reiko M. Nakamura         |
| Group Art Unit         | 1641                      |
| Examiner Name          | Gabel, Gailene            |
| Attorney Docket Number | 10960-0112 (43925-259755) |

|                      | U.S. PATENT DOCUMENTS |   |             |   |  |   |  |  |
|----------------------|-----------------------|---|-------------|---|--|---|--|--|
|                      |                       | U.S. Patent Document Kind Code <sup>3</sup> |             | Name of Patentee or Applicant                   | Date of Publication of<br>Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |  |  |
| Examiner<br>Initials | Cite<br>No.           | Number                                      | (if known)  | Name of Patentee or Applicant of Cited Document | MM-DD-YYYY                               | Figures Appear  |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      | -                     |   | -           |   |  |   |  |  |
|                      |                       |   | <del></del> |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             | ·   |  |   |  |  |
|                      |                       | <del></del>                                 |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      | :                     |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |
|                      |                       |   |             |   |  |   |  |  |

|                      |              |        |                  | FOR | REIGN PATENT DOCUMEN                               | ITS  |  |
|----------------------|--------------|--------|------------------|-----|--|--|--|
| Examiner<br>Initials | Cite<br>No.1 | Office | Foreign Patent D |     | Name of Patentee or<br>Applicant of Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines, ,<br>Where<br>Relevant Passages or<br>Relevant Figures Appear |
| m                    | 1            | JP     | 01-243997        |     | Ajinomoto Co., Inc.                                | 09-28-1989   |  |
| ENTY                 | 2            | JP     | 06-169758        |     | Cosmo Sogo Kenkyusho: KK                           | 06-21-1994   | Apstract Enly  |
| // 0                 |              |        |                  |     |  |  | ,  |
|                      |              |        |                  |     |  |  |  |
|                      |              |        |                  |     |  |  |  |
|                      |              |        |                  |     |  |  |  |
|                      |              |        |                  |     |  |  |  |
|                      |              | ļ!     |                  |     |  |  |  |
|                      |              |        |                  |     |  |  |  |
|                      | 1            |        |                  | l l |  |  |  |

| Signature D' Considered 11/5/64 | Examiner<br>Signature | Brilene | B. | Sabel | Date<br>Considered | 11 | 15/04 |  |
|---------------------------------|-----------------------|---------|----|-------|--------------------|----|-------|--|
|---------------------------------|-----------------------|---------|----|-------|--------------------|----|-------|--|

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁴Applicant is to place a check mark here if English language translation is attached.

PTO/SB/08B (08-00)
Approved for use through 10/31/2002 OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449/A/PTO

JAN 2 2 2004

(use as many sheets as necessary

Sheet 2 of 2

| Cor                    | nplete if Known           |
|------------------------|---------------------------|
| Application Number     | 09/877,802                |
| Filing Date            | June 6, 2001              |
| First Named Inventor   | Reiko M. Nakamura         |
| Group Art Unit         | 1641                      |
| Examiner Name          | Gabel, Gailene            |
| Attorney Docket Number | 10960-0112 (43925-259755) |

|                      |              | OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS  |                |
|----------------------|--------------|--|----------------|
| Examiner<br>Initials | Cite<br>No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journat, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher (it), and/or county where published. | T <sup>2</sup> |
| sny                  | 3            | HARBOE ET AL., "Properties of Proteins MPB64, MPB70, and MPB80 of <i>Mycobacterium bovis</i> BCG", Infection and Immunity, Vol. 52, No. 1, p. 293-302, 1986.   |                |
| grg                  | 4            | NAGAI ET AL., "Specific Skin-Reactive Protein from Culture Filtrate of Mycobacterium bovis BCG", Infection and Immunity, Vol. 31, No. 1, p. 1152-1160, 1981.   |                |
| grey                 | 5            | WIKER ET AL., "MPB59, a Widely Cross-Reacting Protein of Mycobacterium bovis BCG", Int. Archs Allergy appl. Immun., Vol. 81, No. 4, p. 307-314, 1986.  |                |
|                      |              |  |                |
|                      |              |  | ļ              |
|                      |              |  |                |
|                      |              |  |                |
|                      |              |  |                |
|                      |              |  |                |
|                      |              |  |                |
|                      |              |  |                |
|                      |              |  |                |

| Examiner Signature Barlere A. Dabel | Date<br>Considered | 11/15/04 |
|-------------------------------------|--------------------|----------|
|-------------------------------------|--------------------|----------|

<sup>&</sup>lt;sup>1</sup>Unique citation designation number. <sup>2</sup>Applicant is to place a check mark here if English language translation is attached.

PTC/SB/08A (08-0)

Approved for use through 10/31/2082 OMB 0851-064

U.S. Patent and Trademark Office: U.S. DEPARTMENT of COMMERCE
t to a collection of information unless it contains a valid OMB control number

Under the Paperwork Reduction Act of 1995, no persons are requir

om 1449/A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary

of Sheet

| ed to respond to a confection of miles | HEROIT CHILDER IT COMMENTS IN TORIS CHILD DEMINOTE | -        |
|--|--|----------|
| Cor                                    | nplet if Known                                     | 2        |
| Application Number                     | 09/877,802   | حع       |
| Filing Date                            | June 6, 2001                                       | C        |
| First Named Inventor                   | Reik M. Nakamura                                   | _ '      |
| Group Art Unit                         | 1641   | 2        |
| Examiner Name                          | Gabel, G.  | <b>惹</b> |
| Attorney Docket Number                 | 10960-0112 (43925-259755)                          | Z        |

|                      | <del></del>  | U.S. Pater                                       | nt Document                       | U.S. PATENT DOCUMENT                            | Date of Publication of       | Pages, Columns, Lines, Where  |
|----------------------|--------------|--|-----------------------------------|---|------------------------------|---|
| Examiner<br>Initials | Cite<br>No.1 | Number   | Kind Code <sup>2</sup> (if known) | Name of Patentee or Applicant of Cited Document | Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
| 11110013             | 1            | 4,965,192  |                                   | Maes  | 10/23/90                     | *   |
|                      |              |  |                                   |   |                              |   |
|                      | <del></del>  |  |                                   |   |                              |   |
|                      |              |  |                                   |   |                              |   |
|                      |              |  |                                   |   |                              |   |
|                      |              |  |                                   |   |                              |   |
|                      |              |  |                                   |   |                              |   |
|                      |              |  |                                   |   |                              |   |
|                      |              | -  |                                   |   |                              |   |
|                      |              |  |                                   | -   |                              |   |
|                      |              |  |                                   |   | ·                            |   |
|                      |              |  |                                   |   |                              |   |
|                      |              | <u> </u>   |                                   |   |                              |   |
|                      |              | <del>                                     </del> |                                   |   |                              |   |
|                      |              | <del>                                     </del> |                                   |   |                              |   |
|                      |              | <del> </del>                                     |                                   |   |                              |   |
|                      |              |  |                                   |   |                              |   |

|                      |              |                     |   | FOR | EIGN PATENT DOCUMEN                                | ITS  |  |          |
|----------------------|--------------|---------------------|---|-----|--|--|--|----------|
| Examiner<br>Initials | Cite<br>No.1 | Office <sup>3</sup> | Foreign Patent Doc<br>Number <sup>4</sup> |     | Name of Patentee or<br>Applicant of Cited Document | Date of Publication of<br>Cited Document<br>MM-DD-YYYY | Pages, Columns, Lines,<br>Where<br>Relevant Passages or<br>Relevant Figures Appear | 14       |
| spej                 | 2            | PCT                 | WO 96/40236                               |     | National Jewish Center for<br>Immunology           | 12/19/96   |  |          |
| grig                 | 3.           | EP                  | 0199362 A2                                |     | Massachusetts Institute of Technology              | 4/25/86  |  |          |
| <del>(1)</del>       | 4 1          | PCT                 | WO 95/34328                               | Al  | Royer  | 12/21/95   |  |          |
| ang                  | 5            | JP                  | [1997] 920609                             | 92  | Kawajiri   | 8/12/97  | parslation   | <u> </u> |
|                      |              |                     |   |     |  |  |  | 1        |
|                      |              |                     |   |     |  |  |  | +        |

| Signature Considered Considered | Examiner<br>Signature | Duilene | p. Salul | Date<br>Considered | 11/15/04 |
|---------------------------------|-----------------------|---------|----------|--------------------|----------|
|---------------------------------|-----------------------|---------|----------|--------------------|----------|

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WiPO Standard ST.3). <sup>4</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached.

Substitute for Form 1449/A/PTO

Sheet

. 1

## **INFORMATION DISCLOSURE** STATEMENT BY APPLICANT

(use as many sheets as necessary

of

PTO/SB/08A (08
Approved for use through 10/31/20R OMB 0851-0
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMER
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid Orde control approved to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid Orde control approved for use through 10/31/20R OMB 0851-0

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMER **Application Number** 09/877,802 Filing Date June 6, 2001 First Named Inventor Reiko M. Nakamura 1641 **Group Art Unit** Gabel, G. **Examiner Name** 10960-0112 (43925-259755) Attorney Docket Number

|                      |              | OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS  |         |
|----------------------|--------------|--|---------|
| Examiner<br>Initials | Cite<br>No.1 | include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published   | Т2      |
| 8-4                  | 6            | Haga, et al., Difference in Delay Skin Reaction to MPB64 Between BCG-Immunized and Tubercle Baccil-Infected Guinea Pigs, Tubercle and Lung Disease, Vol. 75, Supplement 1, p. 54, 28th World Conference of IUATLD/UICTMR, Mainz, Germany, June 14-17, 1994   |         |
| grag                 | 7            | Haga, et al., Effective Isolation of MPB64 from a Large Volume of Culture Filtrate of Mycobacterium Bovis BCG Tokyo, JPN. J. Med. Sci. Biol., Vol. 49, pp. 15-27 (1996).   | ,       |
| Grap                 | 8            | Haga et al., Delayed Type Hypersensitivity to a recombinant mycobacterial antigen, MPB64, in guinea pigs sensitized to Mycobacterium tuberculosis or Mycobacterium bovis BCG, Journal of Leukocyte Biology, Vol. 57, pp. 221-225 (1995).   |         |
| greg                 | 9            | Nakamura, et al., Tuberculosis Diagnosis with MPB64 - Preliminary Study with a human being, Kekkaku (Tuberculosis)*, The Japanese Society for Tuberculosis, February 15, 1996. Discusses results of preliminary studies conducted to test efficacy of MPB64 antigen administered to skin surface by way of hydrophilic ointment. Results were inconclusive and ointment was not defined.  No function of constitution of telescope Constitution. | J<br>ed |
| 88                   | 10           | Wilcke, et al., Clinical Evaluation of MPT-64 and MPT-59, two proteins secreted from Mycobacterium tuberculosis, for skin test reagents, Tubercule and Lung Disease, Vol. 77, pp. 250-256 (1996).  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
| ············         |              |  |         |
| <del> ,, -</del> -   |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
|                      |              |  |         |
| -                    |              |  |         |
|                      |              |  |         |
|                      |              |  |         |

PTC/SB/08A (08-00)

Approved for use through 10/31/2002 OMB 0851-0031

U.S. Patent and Tradamark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1985, no persons are required to respond to a collection of information unless it contains a yallo OMB control number Complete if Known

| 1            |             |                     |        |               |  | ~~.       |  |   |  |
|--------------|-------------|---------------------|--------|---------------|--|-----------|--|---|--|
| Substitute i | or Form 14  | 49/A/PTO            |        |               | Application Number Filing Date First Named Inventor Group Art Unit |           | 09/877,802<br>June 6, 2001<br>Nakamura |   |  |
|              |             |                     |        |               |  |           |  |   |  |
|              |             | RMATION I           |        |               |  |           |  |   |  |
| 1            | STAT        | EMENT BY            | APPLIC | ANT           |  |           |  |   |  |
| `            | J.A.        | (use as many sheets |        |               |  |           | Gabel                                  | Gabel   |  |
| Sheet        | 1           | of 1                |        | <del></del> - | Attorney Docket  | Number    | 19626-0                                | 112 (45454-259755)  |  |
| Succe        | <u> </u>    |                     |        |               |  |           |  |   |  |
|              |             |                     |        | U.S. PATEN    | T DOCUMENT   | S         |  |   |  |
| Examiner     | Cila        | U.S. Patent         |        | Name of Pa    | entee or Applicant<br>d Document                                   | Date of F | oblication of Document OD-YYYY         | Pages, Columns, Lines, Where<br>Relevant Pessages or Relevant<br>Figures Appear |  |
| Sngr         | 1           | 6,120,776           |        | Haslov et al. |  | 09/19/2   | .000                                   |   |  |
| 0'6          | <del></del> |                     |        |               |  |           |  |   |  |
| F            | <b></b>     | <u> </u>            |        |               |  |           |  |   |  |
|              |             |                     |        |               |  |           |  |   |  |

| Examiner<br>Intlials | Cita | Number       | Kind Cude* (if known) | Name of Patentee or Applicant of Cited Document | Cited Document<br>MM-DD-YYYY | Relevant Passages or Relevant<br>Figures Appear |
|----------------------|------|--------------|-----------------------|---|------------------------------|---|
| Sner                 | 1    | 6,120,776    |                       | Haslov et al.                                   | 09/19/2000                   |   |
| 0'1                  |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      | <del> </del> |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      | <del>}</del> |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      | 1            |                       |   |                              |   |
|                      |      |              |                       |   |                              |   |
|                      |      | <u> </u>     |                       |   | · ·                          |   |
|                      |      |              |                       |   |                              |   |
| ابست وسندون          |      | <del></del>  |                       |   |                              |   |

|                      | Cille<br>No.1 | Foreign Patent Document                          |         |                          | IGN PATENT DOCUME                                  | Date of Publication of       | Pages, Columns, Lines, Where<br>Relevant Passages or | T  |
|----------------------|---------------|--|---------|--------------------------|--|------------------------------|--|----|
| Examiner<br>Initials |               | Office 1   | Number* | Kind Code"<br>(if known) | Name of Patentee or<br>Applicant of Cited Document | Cited Document<br>MM-DD-YYYY | Relevant Figures Appear                              | Τ* |
|                      |               |  |         |                          |  |                              |  | L  |
|                      |               | ++   |         |                          |  | <del>- </del>                |  | ļ  |
|                      |               |  |         |                          |  |                              |  | İ  |
|                      |               |  |         |                          |  | _ <del> </del>               |  | L  |
|                      |               | ╂  |         | <del></del>              |  | <del></del>                  |  | ŀ  |
|                      |               | <del>                                     </del> |         |                          |  | <del></del>                  |  | ł  |
|                      |               | 1-1-   |         |                          |  | 1.                           |  | t  |

| Examiner  | Anilere | a n. 6.0 | Date       | 11/8/11/ |
|-----------|---------|----------|------------|----------|
| Signature | ONIXON  | 19. Jane | Considered | 11/0/04  |

<sup>1</sup>Unique citation designation number. <sup>1</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3), <sup>1</sup>For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>5</sup>Applicant is to place a check mark here if English language translation is attached.